PTO/SB/21 (09-04)
Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Ider the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

#### Application Number 10/692764-Conf. #8952 Filing Date **TRANSMITTAL** October 24, 2003 First Named Inventor **FORM** Stuart B. LEVY Art Unit 1614 (to be used for all correspondence after initial filing) Examiner Name Not Yet Assigned Attorney Docket Number PAZ-205CP Total Number of Pages in This Submission

	ENCLOSURES (Check all tha	at apply)		
Fee Transmittal Form	Drawing(s)	After Allowance Communication to TC		
Fee Attached	Licensing-related Papers	Appeal Communication to Board of Appeals and Interferences		
Amendment/Reply	Petition	Appeal Communication to TC (Appeal Notice, Brief, Reply Brief)		
After Final	Petition to Convert to a Provisional Application	Proprietary Information		
Affidavits/declaration(s)	Power of Attorney, Revocation Change of Correspondence Add	Iress Status Letter		
Extension of Time Request	Terminal Disclaimer	X Other Enclosure(s) (please Identify below):		
Express Abandonment Requi	est Request for Refund	Return Receipt Postcard PTO form SB/08		
X Information Disclosure Stater	nent CD, Number of CD(s)	Certificate of Mailing Copies of Twenty-two (22)		
Certified Copy of Priority Document(s)	· Landscape Table on CD	Landscape Table on CD References		
Reply to Missing Parts/ Incomplete Application	Remarks			
Reply to Missing Parts 37 CFR 1.52 or 1.53.	under			
SI	GNATURE OF APPLICANT, ATTORNE	EY, OR AGENT		
Firm Name LAHIVE & CO	CKFIELD, LLP			
Signature	We hu			
Printed name Cynthia M. Sc	roos			
Date June 6, 2006	Re	g. No. 53,623		

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the U.S. Postal Service on the date shown below with sufficient postage as First Class Mail in an envelope addressed to: MS Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.
Dated: June 6, 2006 Signature: (Cynthia M. Soroos)

PTO/SB/92 (09-04) Approved for use through 07/31/2006. OMB 0651-0031 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Attorney Docket No.: PAZ-205CP

the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Application No. (if known): 10/692764

# Certificate of Mailing under 37 CFR 1.8

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to:

> MS Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

June 6, 2006

Date	
Cepitlui hi	J
Signa	ture
Cynthia M.	Soroos
Typed or printed name of p	erson signing Certificate
53,623	(617) 227-7400
Registration Number, if applicable	Telephone Number

Note: Each paper must have its own certificate of mailing, or this certificate must identify each submitted paper.

Return Receipt Postcard Transmittal (1 page) Information Disclosure Statement (3 pages, in duplicate) PTO form SB/08 (77 References) (3 pages) Copies of Twenty-two (22) References

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the U.S. Postal Service on the date shown below with sufficient postage as First Class Mail, in an envelope addressed to: MS Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA

Dated: June 6, 2006

Signature:

Docket No.: PAZ-205CP

(PATENT)

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

fe Patent Application of: Stuart B. Levy et al.

Application No.: 10/692764

Confirmation No.: 8952

Filed: October 24, 2003

Art Unit: 1614

For:

METHODS OF USING SUBSTITUTED TETRACYCLINE COMPOUNDS TO

Examiner: Not Yet Assigned

MODULATE RNA

#### **INFORMATION DISCLOSURE STATEMENT (IDS)**

MS Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 CFR 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

This Information Disclosure Statement is filed before the mailing date of a first Office Action on the merits as far as is known to the undersigned (37 CFR 1.97(b)(3)).

Applicant has not submitted copies of each cited U.S. patent and U.S. patent application in accordance with 37 CFR 1.98(a)(2)(ii). Applicant submits herewith copies of foreign patents and non-patent references in accordance with 37 CFR 1.98(a)(2).

In accordance with 37 CFR 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR 1.56(a) exists. In accordance with 37 CFR 1.97(h), the filing of this Information Disclosure Statement shall not be construed to be an admission that any patent,

Application No.: 10/692764 Docket No.: PAZ-205CP

publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

### Applicants bring to the Examiners's attention the following co-pending applications:

U.S. Serial No.	10/786710	Filing Date	February 24, 2004
U.S. Serial No.	10/652712	Filing Date	August 28, 2003
U.S. Serial No.	11/305048	Filing Date	December 16, 2005
U.S. Serial No.	11/397445	Filing Date	April 4, 2006
U.S. Serial No.	10/853635	Filing Date	May 24, 2004
U.S. Serial No.	10/738862	Filing Date	December 16, 2003
U.S. Serial No.	10/839023	Filing Date	May 04, 2004
U.S. Serial No.	10/921580	Filing Date	August 18, 2004
U.S. Serial No.	10/692563	Filing Date	October 24, 2003
U.S. Serial No.	10/943571	Filing Date	September 16, 2004
U.S. Serial No.	10/996119	Filing Date	November 22, 2004
U.S. Serial No.	11/283571	Filing Date	November 18, 2005
U.S. Serial No.	10/619653	Filing Date	July 14, 2003
U.S. Serial No.	10/636437	Filing Date	August 6, 2003
U.S. Serial No.	11/292552	Filing Date	December 2, 2005
U.S. Serial No.	10/752378	Filing Date	January 5, 2004
U.S. Serial No.	10/737361	Filing Date	December 15, 2003
U.S. Serial No.	10/740961	Filing Date	December 18, 2003
U.S. Serial No.	11/182247	Filing Date	July 14, 2005
U.S. Serial No.	11/004559	Filing Date	December 3, 2004
U.S. Serial No.	10/616531	Filing Date	July 9, 2003
U.S. Serial No.	10/982728	Filing Date	November 4, 2004

Application No.: 10/692764 Docket No.: PAZ-205CP

U.S. Serial No.	10/819343	Filing Date	April 5, 2004
U.S. Serial No.	10/820456	Filing Date	April 7, 2004
U.S. Serial No.	10/866220	Filing Date	June 10, 2004
U.S. Serial No.	11/300917	Filing Date	December 15, 2005
U.S. Serial No.	11/069197	Filing Date	February 25, 2005
U.S. Serial No.	11/390902	Filing Date	March 28, 2006
U.S. Serial No.	10/786881	Filing Date	February 24, 2004
U.S. Serial No.	10/877928	Filing Date	June 25, 2004
U.S. Serial No.	10/877454	Filing Date	June 25, 2004
U.S. Serial No.	11/330700	Filing Date	January 12, 2006
U.S. Serial No.	11/258622	Filing Date	October 25, 2005
U.S. Serial No.	11/258613	Filing Date	October 25, 2005
U.S. Serial No.	11/348608	Filing Date	February 6, 2006
U.S. Serial No.	11/039230	Filing Date	January 18, 2005

It is submitted that the Information Disclosure Statement is in compliance with 37 CFR 1.98 and the Examiner is respectfully requested to consider the listed references.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 12-0080, under Order No. PAZ-205CP. A duplicate copy of this paper is enclosed.

Dated: June 6, 2006

CMS/MLR/mch

Respectfully submitted,

Cynthia M. Soroos Registration No.: 53,623

LAHIVE & COCKFIELD, LLP

28 State Street

Boston, Massachusetts 02109

(617) 227-7400 (617) 742-4214 (Fax)

Attorney/Agent For Applicant



PTO/SB/08a/b (07-05)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/B/PTO

## **INFORMATION DISCLOSURE** STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 3

Complete if Known			
Application Number	10/692764-Conf. #8952		
Filing Date	October 24, 2003		
First Named Inventor	Stuart B. LEVY		
Art Unit	1614		
Examiner Name	Not Yet Assigned		
Attorney Docket Number	PAZ-205CP		

			U.S. PA	TENT DOCUMENTS	
Examiner Initials*	Cite No.1	Document Number  Number-Kind Code <sup>2</sup> ( if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	A1*	US-5,563,130	10-08-1996	Backer et al.	
	A2*	US-5,567,963		Rao	
	A3*	US-5,574,026		Backer, et al.	
	A4*	US-5,668,122	09-16-1997	4—	
	A5*	US-5,837,696	11-17-1998	<del> </del>	
	A6*	US-5,843,925	12-01-1998		
	A7*	US-5,843,995	12-01-1998		
	A8*	US-5,856,315	01-05-1999	Backer et al.	
	A9*	US-5,900,235		Gosselin et al.	
	A10*	US-6,100,248	08-08-2000		
	A11*	US-6,642,270-A1		Nelson et al.	
		US-20020045603-A1	04-18-2002		
		US-6,818,634-A1	08-01-2002		
		US-20020128237-A1	09-12-2002		
		US-20020128238-A1	09-12-2002		
	+	US-20020132798-A1		Nelson et al.	
	A17*	US-6,500,812-A1		Nelson et al.	
		US-6,841,546-A1		Draper et al.	
		US-6,846,939-A1		Nelson et al.	
		US-20030166585-A1		Draper et al.	
	A21*	US-6,617,318		Nelson, M.L., et al.	
	A22*	US-6,624,168		Nelson, M.L., et al.	
	A23*	US-20030186281-A1	10-02-2003	Hillen	
	A24*	US-20030215873-A1		Alekshun et al.	
	A25*	US-20030219407-A1	11-27-2003		
	A26*	US-6,683,068		Nelson, M.L., et al.	
	A27*	US-20040033996-A1	02-19-2004	Nelson et al.	
	A28*	US-20040048835-A1		Nelson et al.	
	A29*	US-20040063674-A1	04-01-2004	Levy et al.	
	A30*	US-20040092490-A1	05-13-2004		
	A31*	US-20040138183-A1	07-15-2004	Nelson et al.	
	A32*	US-20040152674-A1	08-05-2004		
	A33*	US-20040157806-A1	08-12-2004		
	A34*	US-20040214801-A1		Nelson et al.	
	A35*	US-6,818,635		Nelson, Mark L., et al.	
	A36*	US-20040242548-A1	12-02-2004		
	A37*	US-6,833,365-A1	12-21-2004		
	A38*	US-20040266740-A1	12-30-2004		
	A39*		01-27-2005		
	A40*	US-6,849,615-A1	02-01-2005		
	A41*		02-03-2005		
	A42*		02-03-2005		
			02-17-2005		
	A44*		03-31-2005		
	A45*		06-02-2005		

Examiner	Date	
Signature	Considered	

PTO/SB/08a/b (07-05)
Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Complete if Known Substitute for form 1449A/B/PTO Application Number 10/692764-Conf. #8952 INFORMATION DISCLOSURE October 24, 2003 Filing Date STATEMENT BY APPLICANT First Named Inventor Stuart B. LEVY 1614 Art Unit (Use as many sheets as necessary) Not Yet Assigned Examiner Name 2 3 PAZ-205CP Sheet of Attomey Docket Number

A46*	US-20050137174-A1	06-23-2005	Ohemeng et al.	
A47*	US-20050143352-A1	06-30-2005	Nelson et al.	
A48*	US-20050143353-A1	06-30-2005	Nelson et al.	
A49*	US-20050148551-A1	07-07-2005	Nelson et al.	
A50*	US-20050187198-A1	08-25-2005	Nelson et al.	
A51*	US-20050215532-A1	09-29-2005	Levy et al.	
A52*	US-20050250744-A1	11-10-2005	Levy et al.	
A53*	US-20050288262-A1		Bandarage et al.	
A54*	US-7,001,918-A1	02-21-2006	Huss et al.	
A55*	US-7,045,507-A1	05-16-2006	Draper et al.	

	FOREIGN PATENT DOCUMENTS					
Examiner	Cite	Foreign Patent Document	Publication Date	Name of Patentee or	Pages, Columns, Lines, Where Relevant Passages	
Initials*	No.1	Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)		Applicant of Cited Document	or Relevant Figures Appear	T <sup>6</sup>
	B1	WO-92/12717-A2	08-06-1992	Brem, Henry et al.		
	B2	WO-98/31224-A1	07-23-1998	The Research Foundation of State University of New York et al.		
	В3	WO-99/49871-A1	10-07-1999	The Research Foundation of State University of New Yori		
	B4	WO-00/28983-A1	05-25-2000	Collagenex Pharmaceuticals, Inc.		
	B5	WO-01/87823-A1	11-22-2001	Collagenex Pharmaceuticals, Inc.		

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. \* CITE NO.: Those application(s) which are marked with an single asterisk (\*) next to the Cite No. are not supplied (under 37 CFR 1.98(a)(2)(iii)) because that application was filed after June 30, 2003 or is available in the IFW. 'Applicant's unique citation designation number (optional). \* See Kinds Codes of USPTO Patent Documents at <a href="https://www.uspto.gov">www.uspto.gov</a> or MPEP 901.04. \* Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). \* For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. \* Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. \* Applicant is to place a check mark here if English language Translation is attached.

	NON PATENT LITERATURE DOCUMENTS					
Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²			
	C1	Amin, A.R. et al, "Post-transcriptional regulation of inducible nitric oxide synthase mRNA in murine macrophages by doxycycline and chemically modified tetracyclines," <i>FEBS</i> , Vol. 410(2):259-264 (1997)				
	C2	Friedman, Kenneth J. et al, "Correction of Aberrant Splicing of the Cystic Fibrosis Transmembrane Conductance Regulator ( <i>CFTR</i> ) Gene by Antisense Oligonucleotides," <i>The Journal of Biological Chemistry</i> , Vol. 274(51):36193-36199 (1999)				
	C3	Hertweck, Maren et al, "Inhibition of nuclear pre-mRNA splicing by antibiotics in vitro," Eur. J. Biochem., Vol. 269:175-183 (2002)				
	C4	Karras, James G. et al, "Deletion of Individual Exons and Induction of Soluble Murine Interleukin-5 Receptor-α Chain Expression through Antisense Oligonucleotide-Mediated Redirection of Pre-mRNA Splicing," <i>Molecular Pharmacology</i> , Vol. 58:380-387 (2000)				
	C5	Krawczak, Michael et al, "The mutational spectrum of single base-pair substitutions in mRNA splice junctions of human genes: Causes and consequences," <i>Human Genetics</i> , Vol. 90(1-2):41-54 (1992)				

Examiner	Date	
Signature	Considered	

PTO/SB/08a/b (07-05)
Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/B/PTO				Complete if Known	
				Application Number	10/692764-Conf. #8952
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Filing Date	October 24, 2003
				First Named Inventor	Stuart B. LEVY
				Art Unit	1614
	(Use as many sheets as necessary)			Examiner Name	Not Yet Assigned
Sheet	3	of	3	Attorney Docket Number	PAZ-205CP

C6	Lim, Sharlene R. et al, "Modulation of Survival Motor Neuron Pre-mRNA Splicing by Inhibition of Alternative 3' Splice Site Pairing," <i>The Journal of Biological Chemistry</i> , Vol. 276(48):45476-45483 (2001)
C7	Liu, Y. et al, "Inhibition of in vitro splicing of a group I intron of Pneumocystis carnii," J. Euk. Microbiol., Vol. 41:31-38 (1994)
C8	Nakai, K. et al, "Construction of a novel database containing aberrant splicing mutations of mammalian genes," <i>Gene</i> , Vol. 141(2):171-177 (1994)
C9	Nelson, M. et al, "Tetracyclines in Biology, Chemistry and Medicine," Published by Birkhäuser, pp. 177-196 (2001)
C10	Philips, A.V. et al, "RNA processing and human disease," Cellular and Molecular Life Sciences, Vol. 57(2):235-249 (2000)
C11	Sazani, Peter et al, "Systemically delivered antisense oligomers upregulate gene expression in mouse tissue," <i>Nature Biotechnology</i> , Vol. 20:1228-1233 (2002)
C12	Sazani, Peter et al, "Nuclear antisense effects of neutral, anionic and cationic oligonucleotide analogs," <i>Nucleic Acids Research</i> , Vol. 29(19):3965-3974 (2001)
C13	Schroeder, Renée et al, "Modulation of RNA function by aminoglycoside antibiotics," <i>The EMBO Journal</i> , Vol. 19(1):1-9 (2000)
C14	Stoss, Oliver et al, "Misregulation of pre-mRNA splicing that causes human diseases.  Concepts and therapeutic strategies," <i>Gene Therapy and Molecular Biology</i> , Vol. 5:9-30 (2000)
C15	Wei, Yi et al, "Tetracycline Induces Stabilization of mRNA in <i>Bacillus subtilis</i> ," <i>Journal of Bacteriology</i> , Vol. 184(4):889-894 (2002)
C16	Wilton, S.D. et al, "Specific removal of the nonsense mutation from the mdx dystrophin mRNA using antisense oligonucleotides," <i>Neuromuscular Disorders</i> , Vol. 9(5):330-338 (1999)
C17	International Search Report Application No. PCT/US03/33926, dated August 24, 2004

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Examiner	Date
Signature	Considered

<sup>&#</sup>x27;Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.